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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,743	12/12/2000	Wei-min Liu	3298.1	7518
22886	7590	05/26/2004	EXAMINER	
AFFYMETRIX, INC ATTN: CHIEF IP COUNSEL, LEGAL DEPT. 3380 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/735,743	Applicant(s) LIU ET AL.	
	Examiner Marianne P. Allen	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-21, 23-34, 36-47, 49-59, 61-72, 74-85, 87-97 and 99-103 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-21, 23-34, 36-47, 49-59, 61-72, 74-85, 87-97, 99-103 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection on 3/18/04. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/26/04 (amendment after final rejection) has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 103 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

As set forth in the Advisory Action mailed 2/18/04, the language pointed to by applicant in the specification "more than 5000" is not synonymous with the concept of "at least" as set forth in the claim. As such, the claim is considered to constitute new matter.

Claims 1-2, 6-9, 11-12, 14-15, 26-27, 31-34, 36-40, 44-47, 49-53, 56-69, 61-65, 69-72, 74-78, 82-85, 87-91, and 93-103 are rejected under 35 U.S.C. 112, first paragraph, as failing to

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comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1, 26, 39, 64, 77, and 91-103 require an unspecified test statistic. While particular test statistics are disclosed, the specification does not provide guidance on selecting or developing other test statistics for use in the claimed method nor the associated threshold values. It would require undue experimentation for one of ordinary skill in the art to derive additional test statistics that would be appropriate for use in the claimed method. Applicant has argued previously that it is within the skill of the art to develop additional suitable statistics. This assertion is unsupported by any evidence that such developments would have been routine and not require inventive skill, judgment, and decision making on the part of the practitioner. There is no evidence of record that test statistics (including the appropriate threshold values) for intensity differences between perfect match and mismatch probes suitable for determining whether a transcript is present or absent were routinely developed and validated. Given that the particular test statistics and associated threshold values disclosed are applicant's inventive concept, the examiner maintains that this falls outside the bounds of routine experimentation. The specification does not provide guidance or suggestions for other test statistics, particularly those that would have the thresholds and significance levels set forth in the dependent claims.

Claims 1-2, 6-9, 11-12, 14-15, 26-27, 31-34, 36-40, 44-47, 49-53, 56-69, 61-65, 69-72, 74-78, 82-85, 87-91, and 93-103 require a threshold value without reciting how it is determined or its value. Claims 4 and 5 recite two different equations for calculating the threshold value. It

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appears that τ_1 is the threshold value but the claims do not make this clear. Nevertheless, the specification does not disclose the value of the constant, c_1 , nor does it provide guidance on how to determine or calculate the constant. Page 24 gives another equation for threshold; however, several of the variables are undefined. The examples provide particular threshold values for the particular experiments performed but does not disclose how they were selected or computed. In particular, page 40 discloses the parameter with respect to Equation (3c) where $c''_1 = 1.2$. Note that this equation and constant notation do not appear to be present in the specification.

Likewise, claim 26 requires a threshold. Claims 27, 29, and 30 disclose equations for calculating the threshold for the aforementioned testing statistic; however, the specification does not disclose the value of the constant, nor does it provide guidance on how to determine or calculate the constant. With the exception of where the threshold is zero or specifically provided, one of ordinary skill in the art would not know what threshold to use or how to determine it, particularly for an undefined test statistic. Applicant has not explained why the specification would have provided guidance to one of ordinary skill in the art beyond the specifically disclosed threshold values for the particular test statistics disclosed.

The claims require indicating whether a transcript is present based upon a p -value. The claims are considered to be directed to determining the correct answer with respect to presence or absence and eliminating false positives and false negatives. As such, the parameters that would provide such a result must be taught and the claims must contain limitations that would lead to this result. Many of the claims do not require a particular significance level for the p -value to make this determination.

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Claims 39-47, 49-51, 52-59, 64-72, and 74-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 64 remain confusing as to whether the software product of the preamble is an integrated product where the results of one program code are used as input for the next computer program code or whether these are three discrete pieces of software. As set forth in the Advisory Action mailed 2/18/04, applicant has stated that this is the intent but the language of the claims does not make this clear.

Claim Rejections - 35 USC § 103

Claims 1, 39, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart et al. (1996) in view of either Hogg et al. or Hollander et al.

This rejection is maintained for reasons of record.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen
Marianne P. Allen
Primary Examiner 5/25/04
Art Unit 1631

mpa